

REMARKS

A final Office Action was mailed in the above-captioned application on November 26, 2002. In such Office Action claims 1-4, 7 and 11 were pending and finally rejected. An Amendment and Remarks document was filed on January 23, 2003, but the amendment was not entered. This Amendment and Remarks document is submitted in response to said Office Action, and as the required submission with a Request for Continued Examination.

Informality

Claim 4 has been amended to recite “The method of Claim 1,” to correct an inadvertent typographical error.

The Rejection under 35 U.S.C. § 103(a)

The Examiner has finally rejected Claims 1-4, 7 and 11 under 35 U.S.C. § 103(a) as being unpatentable over Mak, et al., CABA database AN 1999:136034 (1999), and Veech (U.S. Patent No. 6,316,038). The Examiner bears the burden of establishing a *prima facie* case of obviousness (Section 103). In determining obviousness, one must focus on Applicant's invention as a whole. *Symbol Technologies Inc. v. Opticon Inc.*, 19 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1991). The primary inquiry is:

whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have had a reasonable likelihood of success Both the suggestion and the expectation of success must be found in the prior art, not in the applicant's disclosure.

In re Dow Chemical, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

The Examiner asserts that “Mak et al. teaches that a ketogenic diets are known to improve cognitive functioning, see abstract.” The Examiner also asserts that:

“Veech (USPN 6,316,038) teaches a method for treating Alzheimer's disease and it's symptoms and manifestations, including dementia, employing a ketogenic (medium chain triglycerides) diet, see col. 3, lines 21-59 in particular. Veech (USPN 6,316,038) teaches an example of a ketogenic diet wherein at each of the three meals the patient consumes 48-50 g of fat, see particularly co. 10, lines 56-67. Veech (USPN 6,316,038) further teaches that increase of ketone bodies is effective in the treatment of Alzheimer's disease, se particularly col 5, lines 11-29. Veech also teaches that both oral and parenteral administration of

triglycerides can increase blood ketones, see col 9. lines 62-65, see also col. 20, lines 16-23.”

The Examiner further asserts that the present claims are inclusive of ketogenic diets and do not exclude the dietary regimens taught by the prior art cited.

Although Applicant maintains that the claims are nonobvious for the reasons presented in the previous office action response, Applicant has amended Claim 1 to provide the steps of a) providing a patient having a diet wherein carbohydrate intake is not restricted, and b) administering an effective amount of medium chain triglycerides to said patient, in order to clarify the claim. It is believed that Claims 1 and 11, as amended, and dependent claims 4-7 are not obvious in light of the prior art.

The present claims are directed toward a method of treating or preventing dementia of Alzheimer’s type, or other loss of cognitive function caused by reduced neuronal metabolism, comprising administering an effective amount of medium chain triglycerides or a medium chain triglyceride prodrug thereof to a patient in need thereof.

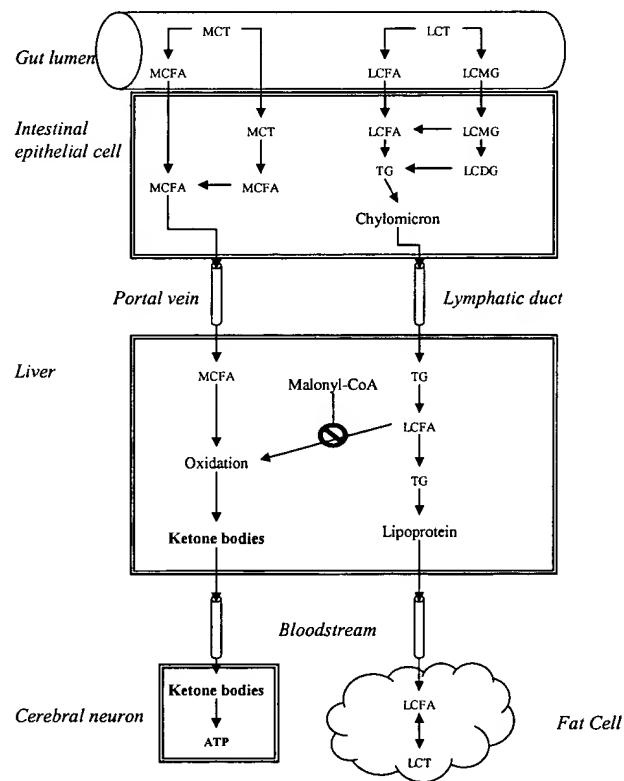
In contrast, the cited passages in the prior art references refer to ketogenic diets. Veech, at column 10, lines 56-68 describes the “classic” ketogenic diet, while Mak, et al. describes a medium chain triglyceride (MCT) oil ketogenic diet.

As pointed out by Mak, et al., and Veech, the ketogenic diet is a high fat, low carbohydrate, low protein, regimen. Veech explains, at column 11, lines 47-54 that carbohydrate ingestion must be avoided in a ketogenic diet due to the metabolic consequences associated with carbohydrate ingestion, namely, an unwanted drop in blood ketones and the esterification of lipids to triglycerides in the liver.

Both Mak, et al, and Veech provide descriptions of ketogenic diets in which fat is high and carbohydrates are limited. In summary, although Mak, et al., and Veech provide that the intake of high amounts of fat, whether long-chain or medium-chain triglycerides, can increase blood ketone levels, this result occurs only in the context of a highly-regimented diet in which carbohydrate levels are limited. Veech explicitly states at col. 9, lines 62-65, that “Either oral or parenteral administration of free fatty acids or triglycerides can increase blood ketones, *provided carbohydrate and insulin are low to prevent re-esterification in adipose tissue.*” (emphasis added). Similarly, Mak, et al., at p. 98, column 2, teaches that “protein was given as 1.5-2 gm/kg/day, carbohydrates were

given in terms of less than 19% of the total calorie requirement. Total calories supplied from protein and carbohydrates should not have exceeded 29% of the total daily calorie requirement.”

The instant specification at page 8 similarly describes that normally the body produces small amounts of ketone bodies, and that a low carbohydrate diet and fasting result in increased blood ketone levels. The specification at page 9-10 explains the differences between medium chain triglycerides (MCTs) and long chain triglycerides (LCT) and their metabolic fate. The specification explains that MCTs are quickly converted to medium chain fatty acids, whose major metabolic fate is oxidation to large amounts of ketone bodies *regardless of the metabolic state of the organism*. The following scheme shows the differences in MCT and LCT metabolism:



Thus, contrary to the teachings of Mak, et al., and Veech, et al., the instant specification teaches that administration of MCT outside the context of the ketogenic diet can raise blood ketone levels.

Accordingly, Claims 1 and 11 have been amended to recite a method of treating or preventing dementia of Alzheimer's type, or other loss of cognitive function caused by reduced neuronal metabolism, comprising the steps of a) providing a patient having a diet wherein carbohydrate intake is not restricted, and b) administering an effective amount of a medium chain triglyceride or a medium chain triglyceride prodrug to a said patient.

Nowhere in the instant specification is it taught or suggested that carbohydrate levels be constrained in order to practice the claimed invention. In fact, the specification in the EXAMPLES section provides exemplary formulations which include carbohydrates. Example 2B, for instance, provides a formulation for a powdered beverage utilizing maltodextrin and sucrose. Example 2C teaches a food bar with a high content of corn syrup solids.

In providing that triglycerides can only be administered in a diet of low protein and carbohydrate, the Mak, et al., and Veech references teach away from the present invention, which provides for the use of MCTs when not part of the ketogenic diet.

Neither Mak, et al., nor Veech teach or suggest that MCT's alone, outside the context of the ketogenic diet may be used to treat Alzheimer's disease. On the contrary, the references explicitly teach that carbohydrate intake must be limited. At most, the combination of Mak, et al., and Veech make it "obvious to try" to use an MCT ketogenic diet in the treatment of Alzheimer's disease. It is well-settled that "obvious to try" is an improper consideration in an obviousness rejection. *See Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 91 (Fed. Cir. 1986).

Reconsideration is respectfully requested.

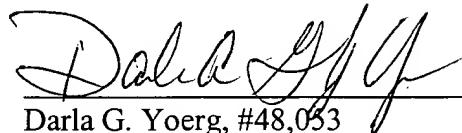
Closing Remarks

Applicant believes that the pending claims are in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117 if not otherwise specifically requested. The undersigned hereby authorizes the charging of any fees created by the

filing of this document or any deficiency of fees submitted herewith to deposit account
No. 19-5117.

Respectfully submitted,



Date: April 28, 2003

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